

TRANSFORMING POST-MARKETING SURVEILLANCE WITH ARTIFICIAL INTELLIGENCE: STAKEHOLDER PERSPECTIVES, BENEFITS, CHALLENGES, AND REGULATORY NEEDS

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RESEARCH QUESTIONS

- Have you encountered any examples of AI being used in PMS?
- What are your biggest concerns about the use of AI in PMS?
- What are the biggest potential benefits of using AI in this field?
- How do you think AI should be regulated to ensure its safe and effective use in healthcare?
- What specific applications of AI do you see as having the most potential in PMS?

INTRODUCTION

Background & Context:

Post-marketing surveillance (PMS) is a critical component of pharmacovigilance, ensuring the continued safety and effectiveness of medicines once they are released into the market. While clinical trials provide preliminary data on a drug's safety and efficacy, certain adverse drug reactions (ADRs) may only become apparent when the medication is used by a larger, more diverse population. Thus, PMS plays an essential role in identifying these risks in real-world settings..

INTRODUCTION (CONTINUED..)

Purpose of the Study:

The purpose of this study is to explore how artificial intelligence (AI) is currently being used in post-marketing surveillance (PMS) in India. It aims to understand the level of awareness among healthcare professionals, students, and pharmacists, and to examine both the benefits and challenges associated with AI use in PMS. The study also provides practical recommendations for the safe and responsible use of AI in this area.

INTRODUCTION (CONTINUED..)

Problem Statement:

Traditional PMS systems in India often face issues such as under-reporting and slow data processing. According to the survey, 78.9% of respondents pointed out these problems. AI can help by enabling real-time analysis and improving efficiency. However, its use raises serious concerns, including data breaches (40.8%), confidentiality risks (27.6%), and system mismanagement (21.1%). These issues underline the need for strong regulatory frameworks and a better understanding of AI's role, especially in rural healthcare settings

INTRODUCTION (CONTINUED..)

AIMS & OBJECTIVES:-

- To examine the awareness and understanding of AI in PMS among healthcare professionals, pharmacists, and students.
- To identify perceived benefits of AI use, such as improved accuracy, faster detection of adverse effects, and reduced costs.
- To recognize major concerns like data privacy, system errors, and lack of trust.
- To explore real-life AI applications, including natural language processing (NLP) and medical image analysis.
- To recommend steps for ethical and safe use of AI in PMS, with attention to accessibility in rural healthcare systems

REVIEW OF LITERATURE

KEY FINDINGS FROM REVIEW OF LITERATURE:-

- Focused on using NLP and machine learning for detecting adverse drug reactions (ADRs); emphasized the need for better regulations(Patel et al.,2025)
- Discussed AI's ability to monitor drug safety in real-time; pointed out challenges in regulation(Kumar et al.,2025)
- Reported AI helps detect safety signals from electronic health records and social media; raised concerns about patient privacy(Gupta et al.,2024)
- 65% of participants believed AI improves ADR detection; 60% were concerned about data privacy (Saxena et al.,2025)
- Recommended global strategies for AI in health surveillance; emphasized the need for consistent international regulations(WHO 2023)
- Supported AI in drug safety systems; highlighted the importance of having validation frameworks(FDA (2024)

METHODOLOGY

Study Design: Descriptive Cross Sectional

Study Duration: February 21 and May 31, 2025

Study Setting: The survey was distributed through professional and academic platforms such as LinkedIn, WhatsApp groups, and institutional networks, reaching participants from urban and semi-urban areas across different Indian states.

Sample Size: 76 respondents
Sampling Technique: Convenience sampling

Study Population: Healthcare professionals, pharmacists, students, managers, analysts

- **Inclusion Criteria:** Individuals aged 21 years and above who are currently working or studying in healthcare, pharmacy, or related fields (e.g., healthcare professionals, pharmacists, students, analysts, managers).
- **Exclusion Criteria:** Those not involved in healthcare or PMS, or unwilling to provide informed consent (e.g., software engineers, patients).

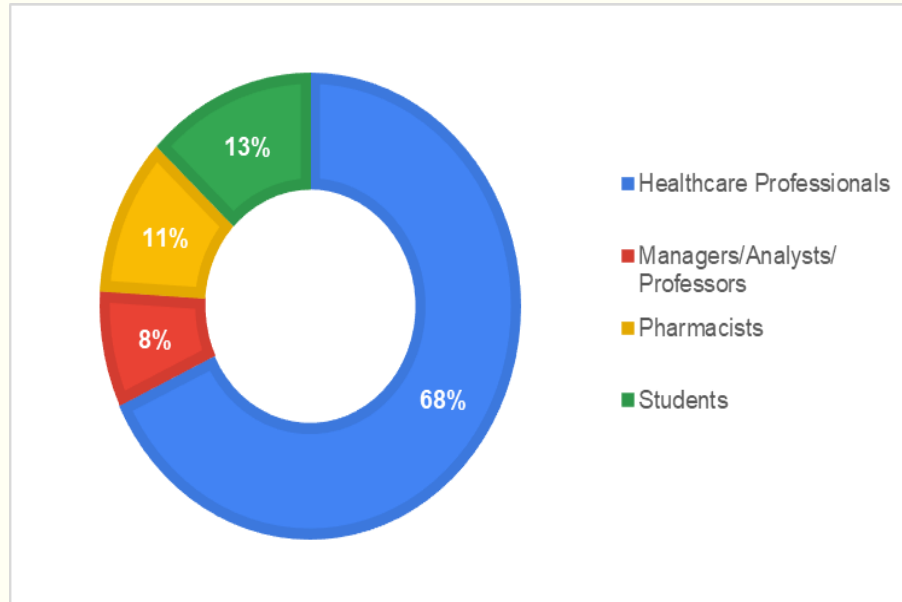
Study Instruments:

The questionnaire was designed and shared via Google Forms. It included both closed-ended and open-ended questions to capture a broad range of responses.

Ethical Considerations:

- Informed Written Consent
- Voluntary Participation
- Confidentiality and Data Security
- Ethical Approval

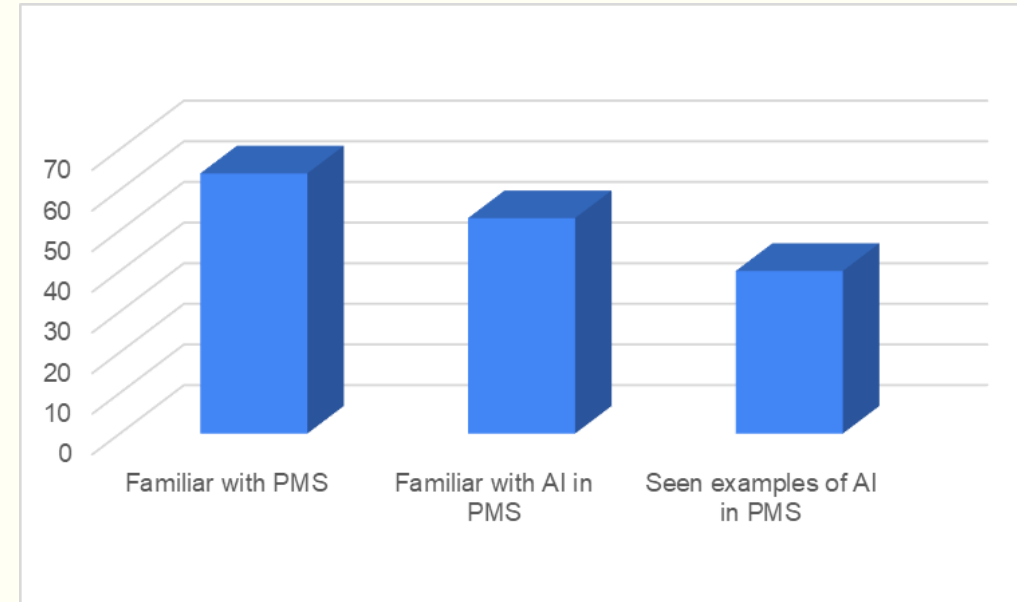
RESULTS



DEMOGRAPHIC BREAKDOWN:

- Healthcare Professionals: 68.4% (52/76)
- Pharmacists: 10.5% (8/76)
- Students: 13.2% (10/76)
- Managers/Analysts/Professors: 7.9% (6/76)

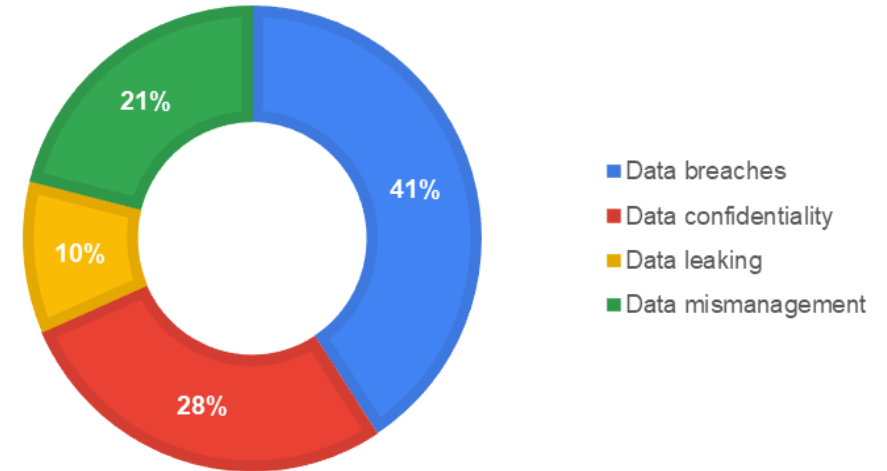
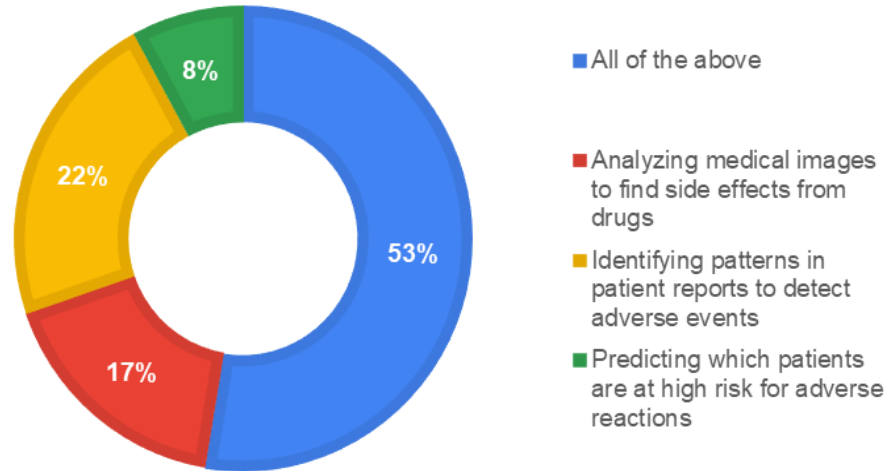
Observation: Clinically rich dataset, limited non-clinical perspectives



AWARENESS OF FAMILIARITY WITH AI:

- 84% familiar with Post-Marketing Surveillance (PMS)
- 70% aware of AI in PMS
- 52% observed AI applications (e.g., image analysis, patient reports, risk prediction)

RESULTS(CONTINUED)...



PERCEIVED AI APPLICATIONS:

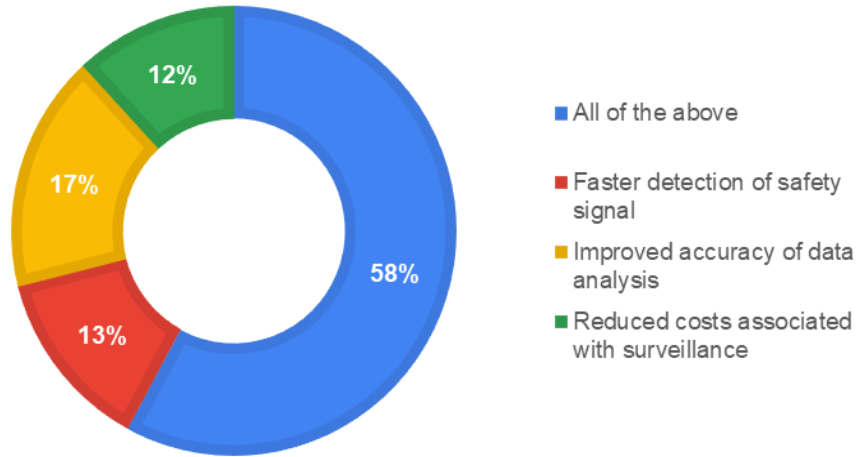
High-Potential AI Uses:

- All applications: 52.6% (40/76)
- Pattern analysis in patient reports: 22.4% (17/76)
- Medical image analysis: 17.1% (13/76)
- Predicting high-risk patients: 7.9% (6/76)

CONCERNS ABOUT AI IN PMS:

- Data breaches: 41% (31/76)
- Confidentiality issues: 28% (21/76)
- Data mismanagement: 21% (16/76)
- Data leaking: 10% (8/76)

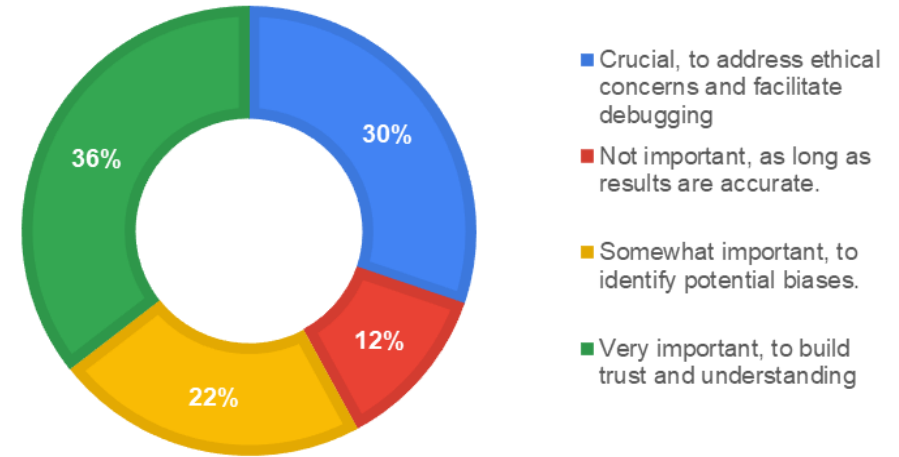
RESULTS(CONTINUED)...



BENEFITS OF AI IN PMS:

Key Benefits:

- Multiple benefits: 57.9% (44/76)
- Faster safety signal detection: 17.1% (13/76)
- Improved accuracy: 13.2% (10/76)
- Reduced costs: 11.8% (9/76)



OPINIONS ON REGULATION OF AI

- Very Important to build trust and understanding: 27 (36%)
- Crucial to address ethical concerns and facilitate debugging: 23 (30%)
- Somewhat important to identify potential biases: 17 (22%)
- Not important as long as results are accurate: 9 (12%)

RESULTS(CONTINUED)...

Chi-square Analysis of Concerns by Role

Role	Data Breaches	Confidentiality	Leaking	Mismanagement
Student	2 (2.86)	0 (1.93)	2 (0.74)	3 (1.47)
Healthcare Professional	25 (22.03)	13 (14.92)	5 (5.68)	11 (11.37)
Pharmacist	2 (3.26)	5 (2.21)	0 (0.84)	1 (1.68)
Managerial	2 (2.86)	3 (1.93)	1 (0.74)	1 (1.47)

observed values

Role	Data Breaches	Confidentiality	Leaking	Mismanagement
Student	2.86	1.93	0.74	1.47
Healthcare Professional	22.03	14.92	5.68	11.37
Pharmacist	3.26	2.21	0.84	1.68
Managerial	2.86	1.93	0.74	1.47

expected values

Variables:

Roles: Students, Healthcare Professionals, Pharmacists, Managers.

Concerns: Data Breaches (41%), Confidentiality (28%), Mismanagement (21%), Data Leaking (10%).

Method: Chi-square test compared observed vs. expected concern counts (SPSS v26).

Results: p-value = 0.680 ($p > 0.05$), indicating no significant association.

Interpretation:

The p-value of 0.680 shows no statistically significant link between roles and concerns.

All roles express similar concerns about data breaches, confidentiality, mismanagement, and leaking.

Data privacy is a universal priority across healthcare stakeholders.

RESULTS(CONTINUED)...

Short Summary of Key Findings:

Most stakeholders (84%) are aware of PMS, and 70% know about AI in PMS, though only 52% have seen examples. Major concerns include data breaches (41%) and confidentiality (28%), while benefits cited include accuracy, speed, and cost savings. The Chi-square test showed no link between role and concern ($p = 0.680$). A majority (66%) support strong ethical AI regulation.

Qualitative insights highlight AI's speed in processing large data, need for transparency, ability to detect patterns in medical imaging, and potential to improve rural healthcare access—underscoring both efficiency and ethical importance.

DISCUSSION

Comparison with Previous Studies:

The findings are consistent with global and national studies. For instance, while Saxena et al. (2025) reported 60% of healthcare professionals expressing privacy concerns, our survey found that 40.8% were concerned about data breaches—indicating similar worries. International literature also confirms AI's capacity to enhance signal detection and optimize ADR monitoring processes, reinforcing our results.

Strengths:

- Study offers a pioneering look to examine Indian healthcare stakeholders' perceptions of AI in PMS.
- Diverse participant base involving professionals from different healthcare roles.
- Combination of quantitative and qualitative insights for a holistic understanding.
- Inclusion of statistical tools (e.g., Chi-square test) to explore variation across roles.

Limitations:

- Convenience sampling limits generalizability across the entire Indian healthcare system.
- Modest sample size (76 respondents) may not capture full diversity of opinions.
- Online format may exclude stakeholders from rural or less tech-savvy areas

CONCLUSION

KEY INSIGHTS:-

High Awareness: 84% familiar with PMS; 70% aware of AI's role; 52% observed AI applications in real-world settings (e.g., image analysis, risk prediction)

Transformative Benefits: AI enhances PMS with faster ADR detection (17.1%), improved accuracy (13.2%), and cost savings (11.8%), with 57.9% recognizing multiple benefits

Universal Concerns: Data breaches (41%), confidentiality (28%), and mismanagement (21%) are shared across roles, highlighting need for robust safeguards

Regulatory Demand: 66% emphasize strong frameworks to ensure trust, ethical use, and transparency in AI-driven PMS

Rural Opportunity: AI can address healthcare disparities by automating data collection in rural India, where resources are limited.

CONCLUSION

IMPLICATIONS:-

Impact on Pharmacovigilance: AI can revolutionize PMS in India by enabling real-time ADR detection, reducing under-reporting, and enhancing drug safety monitoring

Stakeholder Trust: Addressing data privacy and ethical concerns is critical to build confidence among healthcare professionals and patients

Rural Equity: Extending AI to rural settings can bridge healthcare gaps, ensuring equitable access to advanced pharmacovigilance

Global Alignment: Findings align with global trends (e.g., WHO, FDA), reinforcing AI's potential and the need for standardized regulations

Study Significance: First comprehensive survey of Indian stakeholders, providing a benchmark for future AI-PMS research

RECOMMENDATION...

Protect Patient Data

Action: Use strong encryption, secure data storage, and limit access to sensitive health data.

Why: 40.8% of survey participants were worried about data breaches and confidentiality.

Protecting patient information is important to build trust.

Who Should Act: Hospitals, tech companies, and data handlers.

Make Clear AI Rules

Action: Health authorities (like CDSCO) should create clear guidelines on how AI should be used in PMS. These should include rules about safety, ethics, and fairness.

Why: 65.8% of respondents felt that strong regulation is crucial for trust and proper use.

Who Should Act: Government health departments and regulatory bodies.

Educate Stakeholders

Action: Provide training and awareness programs for doctors, pharmacists, healthcare students, and AI users.

Why: Although 69.7% are aware of AI in PMS, many still lack practical knowledge. Education helps everyone use AI responsibly.

Who Should Act: Medical colleges, universities, healthcare institutions.

Ensure Fairness in AI

Action: Check AI tools regularly to make sure they treat all patient groups fairly and are trained on diverse data.

Why: Biased tools can lead to unfair treatment or wrong outcomes.

Who Should Act: AI developers, health data teams, regulators.

RECOMMENDATION(CONTINUED)...

Make AI Transparent

Action: AI tools must show clear, understandable results and explain how decisions are made.

Why: When users can understand how AI works, they are more likely to trust it.

Who Should Act: AI developers and technology providers.

Work Together

Action: Encourage collaboration between healthcare providers, tech companies, researchers, and regulators. Share best practices and data safely.

Why: Joint efforts help develop better AI tools and create common standards, as suggested by WHO (2023).

Who Should Act: Regulators, companies, researchers.

Test AI Before Large-Scale Use

Action: Run pilot projects in hospitals and clinics to test AI tools before using them widely.

Why: Testing in real-world settings helps identify problems and ensures the tool actually works.

Who Should Act: Healthcare institutions, especially in rural and urban areas.

Support More Research

Action: Fund studies that explore new uses of AI in PMS, especially in rural areas where data is often limited.

Why: Research helps improve AI tools and ensures benefits reach all areas, reducing healthcare gaps.

Who Should Act: Research councils, funding agencies, government bodies.

*Thank
You*